CervicalCheck
AN CLÁR NÁISIÚNTA SCAGTHÁSTÁLA CEIRBHEACS
THE NATIONAL CERVICAL SCREENING PROGRAMME

07 August 2018

Dear Colleague,

Further to our letter dated 9 May 2018, we are writing today to all healthcare professionals registered with CervicalCheck with updated advice and information regarding CervicalCheck. You will find a comprehensive document enclosed which should address a number of queries raised by healthcare professionals regarding the current situation.

The HSE's National Screening Service would like to thank our registered healthcare professionals for their ongoing support in this challenging situation and for their continued work to offer support and reassurance to the women who are understandably concerned. We further acknowledge that all those concerned who are based in primary care, colposcopy clinics, family planning clinics, oncology services and other settings have experienced a large increase in workload and complexity of cases which has been dealt with in a most professional manner.

We also hope to have your support in the future as we undertake the work of rebuilding confidence in this important public health programme.

Yours sincerely

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CervicalCheck Update for Health Professionals: July 2018

We have received queries from health professionals about our screening programme and the recent audit. The following information may be helpful for use in practice.

Cervical screening and its limitations

Early detection and treatment, through screening, can prevent around 75 per cent of cervical cancers developing but, like other screening tests, cervical screening is not perfect. It may not always detect early cell changes that may lead to cervical cancer. Furthermore, it is not a diagnostic test and is designed for women without symptoms.
Abnormal cells on slides may not be recognised because:

- sometimes they do not look much different from normal cells;
- there may be very few abnormal cells on the slide; or
- the person reading the slide may miss the abnormality (this happens occasionally, no matter how experienced the reader is).

Cervical screening is not looking for cancer; it is looking for abnormal squamous cells that if left untreated may turn cancerous. 80 per cent of cervical cancers are squamous in origin with usually a pre-invasive phase which makes regular screening useful for this type of cancer. Screening is less efficient at preventing adenocarcinoma of the cervix.
If a woman is experiencing any symptoms (unexplained vaginal bleeding, post coital bleeding, unusual discharge or pelvic pain), she should visit her doctor without delay.
The Information Sheet for Women, attached to each cytology referral form, explains these limitations and should be given to each woman before their screening test. The information sheet is a useful resource which will assist smeartakers to comply with their contractual obligations to ensure women are fully informed of the benefits and limitations of screening before consenting to the test.

Information held by CervicalCheck

CervicalCheck commenced in Ireland in 2008 and only holds information on screening tests carried out by the programme since this time (other than the Mid-West region where the cervical screening programme was phased in). The Programme does not, as standard business, access information about screening tests, colposcopy visits, diagnostic tests or cervical cancers prior to this time or tests taken outside of this country.

Educational Updates

We will continue to provide educational updates on www.nssresources.ie and www.cervicalcheck.ie.

CervicalCheck Policies

- **Repeat smear tests**

All women of screening age are eligible to have a free consultation, and if necessary, a free repeat screening test with CervicalCheck. This is available until 31st December 2018 where a woman has a concern relating to their cervical screening.
Free screening tests are only available with health professionals registered with CervicalCheck. Correspondence in relation to the mechanism for facilitating this free repeat smear test was issued on the 9 May to all health professionals registered with CervicalCheck which outlined how they should claim for the reimbursement of costs.

- **Information for the service user**

Benefits and limitations of cervical screening should be addressed when preparing and counselling women and their informed consent should be gained prior to each screening test. It is policy that the Information Sheet, attached to each cytology referral form, is given to each woman along with explanations about screening, consent, personal data sharing and the screening test itself.

- **Primary screening test**

Currently and until further notice 'cytology' is the primary screening test in CervicalCheck.

- **CervicalCheck Audit**

Approximately 3,000 women in Ireland have been diagnosed with cervical cancer since 2008, and approximately half of these cases were notified to CervicalCheck. The majority of these notifications were received from the National Cancer Registry of Ireland. When CervicalCheck was notified that a woman had been diagnosed with cervical cancer, their previous screening history was reviewed. CervicalCheck carried out an audit of 1,482 previous cervical screening tests on women who were diagnosed with cervical cancer from 2008 to 2017.

- **RCOG Review**

An independent external clinical review was requested by the Minister for Health in May 2018. The review will be carried out under the auspices of the Royal College of Obstetricians and Gynaecologists (RCOG) with expert input from the British Society for Colposcopy and Cervical Pathology. The purpose of the review is to provide women who participated in the national cervical screening programme and who developed invasive cervical cancer with independent clinical information about the timing of their diagnosis and any issues relating to their treatment and outcome. The review will also help to assess the overall quality of the CervicalCheck screening programme. Where appropriate the panel will make recommendations with the aim of improving care for women.

Laboratories

Each cytology laboratory engaged by CervicalCheck is INAB accredited and each test is screened by two trained and qualified cytology screening staff.
The laboratory where each sample is screened is identified on each screening laboratory result communicated to the smeartaker.

- **Review of slides**

CervicalCheck does not have a facility for a 'review' of slides unless as part of a cancer review process. However, any woman who is concerned can avail of a free consultation, and if necessary, a free repeat screening test with CervicalCheck to the end of 2018.
There is no facility to accept, review, comment or make recommendations for non-programme screening tests, i.e. private tests or tests taken outside the country.

- **Smear test vials**

Under no circumstances should the contents of a sample vial be 'divided' and sent to two different laboratories. This is likely to result in a suboptimal screening test.
Please be aware that the expiry date of vials used must be in date by 3-4 weeks. There is a risk that the sample could expire before tested due to increase numbers of tests to the laboratories currently. Samples must be dispatched to the lab within 5 working days of

sample taking. The obligations of smeartakers in Primary Care are outlined in the *Guidelines for Quality Assurance in Cervical Screening – Chapter 3 Quality Assurance in Primary Care* which can be viewed and downloaded from www.cervicalcheck.ie.

Results and Follow Up

- **Delay in smear test results**

The laboratories are experiencing high volumes and a backlog in processing screening tests. Currently the turnaround time is up to 12 weeks for most tests taken since April 2018. CervicalCheck is working with laboratories to reduce these waiting times. To aid resolution, laboratories have brought on additional staff, commenced overtime, tapped into their wider organisation for assistance, and in some cases cancelled annual leave.

- **TZ cells**

Transformation Zone (TZ) cells are not required to be present to deem a smear test as adequate. An absence of TZ cells does not affect re-call in an adequate negative smear test. If a negative result is given, the routine re-call recommendation should be followed. TZ cells may be difficult to sample in postmenopausal women.
Smeartakers should be aware that evidence of TZ sampling is considered to be a measure of smeartaking competency.

- **HPV triage**

HPV triage for the management of low grade abnormalities has been used since 2015. The presence of high risk HPV correlates well with abnormal cytology. A negative HPV test correlates well with normal cytology. As for all screening tests, there is an inherent false positive and false negative rate with HPV primary screening.
A negative HPV test has a very good negative predictive value. The management of the woman is based on the HPV result rather than the cytology result for triage tests (i.e. the HPV result overrides the low grade cytological result).
HPV triage results for a woman who is post colposcopy will override the colposcopy discharge recommendation (e.g. discharge recommendation of 10 x annual tests post treatment, if she is HPV triage negative during this time, a routine recall recommendation is given).

Colposcopy services

Any woman currently attending colposcopy services should continue to be managed at colposcopy. It is inappropriate to rescreen these individuals as their care plan already includes diagnostic, management and follow up measures.
CervicalCheck only receives results electronically by code, this means that any clinical information documented by you, the smeartaker, or incidental findings reported by the laboratory are not visible to us, these findings can include follicular cervicitis, actinomyces, endometrial cells seen in a person over 40. Follow up and management of these incidental findings are based on the individual practice policy. CervicalCheck does not have guidelines for this clinical follow up.

- **Unwarranted colposcopy referrals**

Colposcopy services have reported an increase in the referral rate based on ‘suspicious cervix’. Unwarranted colposcopy referrals lead to overload of the colposcopy service, extended appointment waiting times and distress to those being referred.

Smeartakers should be familiar with the appearance of normal anomalies, e.g. eversions and nabothian follicles. After clearly visualising the cervix, an assessment as to whether there is cause for concern can be made. It is important to note that screening is not diagnostic.
The cervix image library on www.nssresources.ie is a valuable reference point.

Private smear tests

If a private test is undertaken and no recommendation is provided by the laboratory, CervicalCheck cannot provide you with one. For example, if cytology is reported as negative and HPV is detected, this is outside the scope of the programme and we do not have a policy in place to manage these results. The Australian algorithm might prove to be a useful resource in such cases given that HPV Primary Screening has already been introduced there. This information can be sourced at the following weblink:
http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/healthcare-providers

Women who may have symptoms/Indication of clinical suspicion

Screening is designed for women without symptoms.
Colposcopy referrals should be primarily based on results of the screening test undertaken. Remember – clinical suspicion will always override cytological interpretation. This is due to the rapid mitotic nature of cancer cells – which can mimic negative cells.
If a woman is symptomatic with unexplained vaginal bleeding, post coital bleeding, an unusual discharge or pelvic pain, a speculum examination is always required.

New HPV Primary Screening

As per HIQA recommendations there is a need to introduce the more sensitive HPV testing as the primary screening method for the prevention of cervical cancer in Ireland.
A Steering Group has been established by the HSE to oversee the planning and implementation of Primary HPV Screening. A project team, building on the work of team members from the National Screening Service who has been making plans for the HPV rollout since the HIQA recommendation was published in May 2017 is beginning detailed project planning which will result in a timeline for implementation.